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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,364	04/12/2004	Robert Burgmeier	S63.2-10866-US01	3075
490	7590	12/28/2007		
VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,364	<b>Applicant(s)</b> BURGMEIER ET AL.	
	<b>Examiner</b> Bhisma Mehta	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/15/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I in the reply filed on October 17 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 15 and 26. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tie layer between

the balloon and the catheter shaft must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

4. Claims 3-5, 7, 9, and 11-17 are objected to because of the following informalities: Claim 3 recites the limitation "said waist portions" in line 2. Claim 4 recites the limitation "said cone portions" in line 2. Claim 5 recites the limitation "said first layer" in lines 1-2. Claim 7 recites the limitation "said first layer" in line 1. Claim 9 recites the limitation

"said second composition" in line 2. Claim 11 recites the limitation "said waist portion" in line 2. Claims 12 and 13 recite the limitation "said catheter shaft" in line 2. Claim 17 recites the limitation "said cone portion" in line 3. There is insufficient antecedent basis for these limitations in these claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 17, the use of a second layer is unclear as a first layer has not been established.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 8, 11-13, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaneko et al (U.S. Patent No. 5,344,400). Kaneko et al disclose a dilatation balloon with a waist (10), cone, and body portions where the balloon is formed

of a first polymeric composition (18) and a second layer (16) is formed on at least a portion of the balloon. The second layer comprises a second polymeric composition (16). Kaneko et al disclose the second polymeric composition as a polyolefin. The polyolefin is capable of being crosslinked to form a compression region. Kaneko et al also disclose a tie layer (17) between a first layer (18) and the second layer (16). In lines 14-26 of column 5, Kaneko et al disclose the first layer or the first polymeric composition as a polyolefin or a polyester. In lines 53-68 of column 5, Kaneko et al disclose a tie layer between the balloon and the catheter shaft. As to claim 17, Kaneko et al disclose a dilatation balloon with a waist (10), cones, and body portion where the balloon is formed of a first polymeric composition (18) and a second layer (16) on the cone portion of the balloon formed from a second composition.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Dusbabek et al (U.S. Patent No. 5,968,069). Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second composition as polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the first polymeric composition comprising a polyether block amide. Dusbabek et al

disclose a balloon where a first layer (214) comprising a first polymeric composition is formed of a polyether block amide and a second layer comprising a second polymeric composition (251). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the first polymeric composition of Kaneko et al a polyether block amide as taught by Dusbabek et al as both Kaneko et al and Dusbabek et al teach balloons with multiple layers and Dusbabek et al teach that it is well known to use polyether block amide for the first layer.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Smith et al (U.S. Patent No. 6,083,587). Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising polyethylene modified with at least one member. Smith et al disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer. In lines 1-22 of column 5, Smith et al disclose the tie layer as comprising a polyethylene modified with maleic anhydride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a polyethylene modified with maleic anhydride as taught by Smith et al as both Kaneko et al and Smith et al teach medical devices with multiple layers and tie layers between the multiple layers and Smith et al teach that it is well known to use a polyethylene modified with maleic anhydride for the tie layer.

12. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al in view of Branham et al (U.S. Patent No. 6,897,168). Kaneko et al

disclose the balloon substantially as claimed. Even though Kaneko et al disclose the tie layer, Kaneko et al are silent on the specifics of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting temperature than the first polymeric composition. Branham et al disclose multi-layered polymer structures for medical devices where a tie layer or co-binder is formed between a first layer and a second layer. In lines 1-31 of column 13, Branham et al disclose the tie layer as comprising a crosslinking inhibitor and as having a lower melting temperature than the other layers of the device such that crosslinking is impaired when heat is applied. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the tie layer of Kaneko et al a crosslinking inhibitor as taught by Branham et al as both Kaneko et al and Branham et al teach medical devices with multiple layers and tie layers between the multiple layers and Smith et al teach that it is well known to use a crosslinking inhibitor for the tie layer and to use a tie layer which has a lower melting temperature than the other layers of the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

